

Kentec Medical, Inc.
Ameritus® Medical Enteral Feeding Extension Set
Response to December 7, 2011 Questions

FEB 17 2012

SECTION 5 510(k) SUMMARY

Date of Submission: September 26, 2011

Official Contact: Keith Rooks
RA/QA Manager
Kentec Medical, Inc.

Address of Manufacturing

Facility: Kentec Medical Technology Co.
90 Gao Xin Road, ZhouZhuang
Kunshan 215325, China
T: 86 512 5720 0500

Proprietary Name: Kentec Medical Ameritus® Enteral Feeding Extension Set (EFES)

Common/ Usual Name: Gastrointestinal tubes and accessories

Classification Reference: 21 CFR 876.5980

Product Code: KNT

Predicate Devices: NeoMed Enteral Only Extension Set (K100288)
CORFLO Anti-I.V. Enteral Feeding Extension Set (K083786)
CORFLO Anti-I.V. Enteral Feeding Extension Set 20-1060AIV-S (K083791, K083786)

Indication for Use:

The Enteral Feeding Extension Set (EFES) is intended for use as an extension set for nasogastric/ orogastric or gastric tube enteral feeding tubes, incorporating safety connectors which help mitigate the risk of accidental misconnection with an I.V. system to the enteral system or the enteral system to an I.V. system.

Patient Population/ Environment of Use:

The EFES is indicated for use in neonatal and pediatric patients in connection with an enteral feeding tube to provide nutrition via nasal or oral gastric placements.

The Enteral Feeding Extension Set is a sterile disposable for single patient use only.

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Substantial Equivalence

The EFES is substantially equivalent to many commercially available enteral feeding extension sets.

The EFES' indications for use and FDA Product Code/ Classification Codes are identical to the NeoMed Enteral Only Extension Set (K100288) and are substantial equivalent to both the CORPAK MedSystem's CORFLO Anti-I.V. Enteral Feeding Extension Set (K083786) and the CORPAK MedSystem's Anti I.V. Enteral Feeding Extension Set Model # 21-1060AIV-S (K083791).

The Kentec Medical EFES components' biocompatible materials are either identical to, or substantially equivalent to:

- The NeoMed Enteral Only Extension Set (K100288),
- The CORPAK MedSystem's CORFLO Anti-I.V. Enteral Feeding Extension Set (K083786) and/ or
- The CORPAK MedSystem's Anti I.V. Enteral Feeding Extension Set Model # 21-1060AIV-S (K083791).

The EFES' Technical Characteristics, Packaging and Ethylene Oxide Sterilization Characteristics, as well as Labeling Characteristics, are substantially equivalent to:

- The NeoMed Enteral Only Extension Set (K100288),
- The CORPAK MedSystem's CORFLO Anti-I.V. Enteral Feeding Extension Set (K083786) and/or
- The CORPAK MedSystem's Anti I.V. Enteral Feeding Extension Set Model # 21-1060AIV-S (K083791).

The EFES and its components successfully completed in-vitro testing which demonstrated that the device functions according to its specifications (including the *inability* to connect to a Luer connection) and is thus substantially equivalent in function to

- The NeoMed Enteral Only Extension Set (K100288),
- The CORPAK MedSystem's CORFLO Anti-I.V. Enteral Feeding Extension Set (K083786) and/ or
- The CORPAK MedSystem's Anti I.V. Enteral Feeding Extension Set Model # 21-1060AIV-S (K083791).

Design verification tests were performed on the EFES as a result of the risk analysis and product requirements. The following tests and analysis were conducted demonstrating the EFES met the acceptance criteria.

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Specific Test	Test Model	Justification
Extension Set Connector Tensile Test	Kentec Medical EFES, NeoMed Enteral Only Extension Set (K100288) and CORFLO EFES (K083791, K083786) tested	Actual proposed device, predicate (K100288) and predicate (K083791) tested
Extension Set Liquid Leakage Test	EFES, NeoMed Enteral Only Extension Set (K100288) and CORFLO EFES (K083791, K083786) tested	Actual proposed device, predicate (K100288) and predicate (K083791) tested
Luer Connection Testing (anti-IV test connection)	EFES	Actual proposed device tested
Flow Characteristics	EFES	Actual proposed device tested
ISO 80369-1 requirements	EFES	Actual proposed device tested
Size and Material Inspection	EFES	Actual proposed device tested
Biocompatibility Test (EFES materials)	EFES	Actual proposed device tested
Biocompatibility Test (orange colorant)	EFES	Actual proposed device tested
Sterilization Related Test	EFES	Actual proposed device and packaging integrity tested
Storage and Shelf Life Test (accelerated-time aging)	EFES	Actual proposed device and packaging integrity tested
Package Related Test	EFES	Actual proposed device packaging integrity tested

Device Description

The Kentec Medical Enteral Feeding Extension Set (EFES) is a sterile disposable device for single patient use only. The device is designed to connect existing feeding tubes (nasogastric, orogastric, gastric, etc) to various delivery enteral syringes as well as to help minimize the potential for inadvertent delivery of enteral feedings through the intravenous route. i.e., the device cannot be connected to a luer connector.

The device consist of flexible PVC tubing with an orange strip for easy quick identification of enteral feeding lines as well as a "For Enteral Feeding Only" tag and a slide clamp to provide the additional safety assurance for connection errors.

The basic set (OC-ENT-60) consists of tubing with a step connector (catheter tip) and an oral syringe connector not compatible with intravenous (I.V.) tubing or stopcocks. Other variations include:

- The basic set with shorter tubing (OC-ENT-36)
- The basic set with step connector changed into oral syringe connector (2OC-ENT-60)

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- The basic set with the addition of a “Y” site with an oral syringe connector to allow the clinician to attach other equipment.

Connectors

The Enteral Feeding Extension Set (EFES) incorporates safety oral syringe connectors which eliminate the risk of I.V. administration through the feeding tube, i.e., the safety connectors do not mate with Luer Lock or Luer slip fittings.

Analytical comparison and lab testing of the EFES' connector's dimensions to others devices listed in ISO 80369-1 allow the conclusions that:

- The EFES' connectors are substantial equivalent to the NeoMed (K100288) and the CORPAK (K083786, K083791) devices.
- The EFES' oral syringe female connector is not compliant with the ISO 594 standard's (Luer) connector requirements (i.e., does not connect).
- The EFES' oral syringe female connector is not compliant with other small-bore connectors listed in the ISO 80369-1, except for enteral feeding tips.

The EFES connector analytical engineering evaluation demonstrated that the width (inner diameter, ID) of the EFES female connector is much larger than the ISO 594 Male Luer Connector standard I.V. connector outside diameter (OD) dimension [$\Phi 3.925\text{mm}$ - $\Phi 4.027\text{ mm}$]. Thus, the EFES female connector cannot physically fit into an ISO 594 rigid male Luer connector or naturally disengaged without any force, and does not conform to the ISO 594 standard's requirements.

While Kentec Medical has searched for an applicable standard for the dimensions of oral enteral feeding syringes' rigid male connectors, none were found. However, in order for hospital to purchase feeding syringes from a variety of manufactures and be assured that these different devices will all be compatible with the hospitals' existing equipment, the industry utilizes the same male connector OD dimensions, e.g., a “common use” industry standard. To ensure these “common use” dimensions were tested, the EFES was evaluated against two (2) commercially available oral enteral feeding syringes in relation to their connectors.

These analyses demonstrated that the Kentec Medical Enteral Feeding Extension Set dimensions fit well within the male connector of commercially available feeding syringes, e.g., the Philips Children's Medical Venture Oral/Enteral Syringe (K100099), the Kentec Medical Oral/Enteral Syringe (K110853).

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Materials

The Enteral Feeding Extension Sets are manufactured from polyvinyl chloride (PVC) tubing. The connectors, caps, and slide clamps are manufactured of several plastics: PVC, Polypropylene (PP), and Polyethylene (PE). All materials have been evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Device – Part 1: Evaluate and Testing. Based on comparisons to these materials used in other devices, no additional biocompatibility testing was necessary; however, Kentec Medical conducted three confirmatory tests (cytotoxicity, sensitization, and irritation) which confirmed the acceptable biocompatible status of these materials.

The EFES' component materials are substantial equivalent to the materials utilized in the NeoMed (K100288) and the CORPAK (K083786, K083791) devices.

Conclusion

The conclusions drawn from the actual conducted (as well as the referenced) analytical engineering evaluations, the nonclinical tests and the commercial use of similar and predicate devices, demonstrates that the Kentec Medical Enteral Feeding Extension Set (EFES) is as safe and effective as the legally marketed (predicate) devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Kentec Medical, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB 17 2012

Re: K120272
Trade/Device Name: Ameritus® Medical Enteral Feeding Extension Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 27, 2012
Received: January 30, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

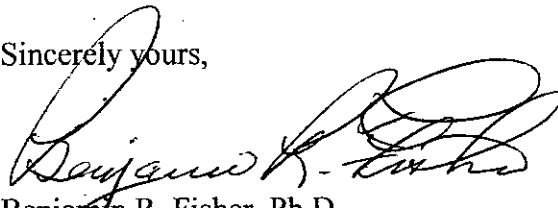
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher".

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

SECTION 4 INDICATION FOR USE STATEMENT

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510(k) Number (if known): K120272

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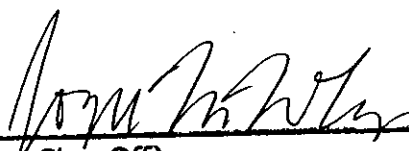
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/ OR

Over-The-Counter Use
(Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K120272

9/29/2011